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APPLICATION NO.	FILING DATE	FIRST NAMED [redacted]VENTOR	ATTORNEY DOCKET NO.
08/325,278	10/26/94	BJORCK	L 216764

000500 HM12/0426
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EXAMINER	
MINNIFIELD,N	
ART UNIT	PAPER NUMBER
1645	33

DATE MAILED: 04/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic(s)
08/325,278	BJORCK ET AL
Examiner	**Group Art Unit**
N. M. Minnifield	1645

☒ Responsive to communication(s) filed on *Dec 18, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *14-20* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *14-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The request filed on December 18, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08325278 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 14-20 are now pending in the present application.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicants' amendment was received and entered as Paper No. 16. However, the amendment to page 5, line 3 was not entered since it is not clear where the phrase "SUMMARY OF THE INVENTION" is to be entered. Additionally, the amendment to page 5, line 26 and page 9, lines 15 and 16 was not entered since the phrase as set forth in applicants amendment were not present on the lines indicated by applicants. Furthermore, the amendment requesting moving the section to page 5, line 21 was not entered as requested. The Examiner requests applicants provide a substitute specification incorporating the amendments as set forth above.

As per 10/12/99 Amendment Applicants have indicated that a substitute specification will be submitted in due course.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14 and 18-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 for the reason set forth in the last Office Action.

Applicants argue the rejection should be withdrawn in view that claims 1-14 of U.S. Patent No. 4,876,194 does not teach the sequence. Applicants' arguments are not sufficient to obviate the rejection. It is reasonable to conclude protein L

as set forth in the issued patent is the same, or in the alternative an obvious or analogous variant of protein consisting of SEQ ID No. 1 as recited in the instant application since they have the same properties (useful as kit, useful as pharmaceutical composition, bind light chains of immunoglobulins, and from *P. magnus* strain 312). Mere discovery that claimed composition possesses property not disclosed for prior art does not ***alone*** defeat prima facie case of obviousness and it is ***not*** necessary in order to establish prima facie case, to show both structural similarity between claimed and prior art compound ***and*** suggestion in, or expectation from, prior art that claimed compound will have same or similar utility as one newly discovered by applicant. See In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990).

For the reasons set forth above and in the last Office Action said rejection is maintained.

Claims 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 in view of Guss et al. (WO 87/05361)(Art Cited by Applicants in the IDS) and Kastern et al. (1990) (Infection and Immunity 58(5):1217-22 5/90) (Art Cited by Applicants in the IDS) for the reason set forth in the last Office action.

Applicants' argument is set forth above. For the reasons set forth above and in the last Office Action said rejection is maintained.

Applicant's arguments filed October 12, 1999 have been fully considered but they are not persuasive. Applicants have asserted that obtaining the sequence of the L protein and identification of particular domains that bind immunoglobulin light chain is unusually difficult. However, Applicants have not set forth any evidence of record to support such an assertion. The rejection is maintained.

6. Claims 14 and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Kastern et al. 1992 (J. Biol.. Chemistry 267(18):12820-25 1992 (Art Cited by Applicants in the IDS)for the reason set forth in the last Office action. Applicants argue the rejection should be withdrawn when a declaration is prepared stating the work of Kastern et al. is that of the named inventors. Until applicants provide a proper declaration said rejection is maintained for the reasons set forth in the last Office Action. This rejection is maintained for the reasons of record.

Applicant's arguments filed October 12, 1999 have been fully considered but they are not persuasive. Applicants have indicated a declaration asserting that Kastern et al is not citeable against the present invention because it is the work of the inventors (declaration under 37 C.F.R. 1.132) will be submitted in due course. The rejection remains until such declaration has been formally made of record in this application file.

7. Claims 14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 255 497 (Art Cited by Applicants in the IDS) or US Patent No. 4,876,194 ('194) (Art Cited by Applicants in the IDS).

The teachings of both references have been set forth in previous Office Actions, see paper number 14. The references teach the protein L and that the protein binds the light chains of immunoglobulins as claimed by Applicants except for the sequence. However, the mere discovery of a claimed sequence does not distinguish over the prior art if the prior art disclose other characteristics of the claimed invention. It is noted that the proteins of the cited prior art references were not characterized by the references as having a specific amino acid sequences. However, the mere discovery of an amino acid sequence, molecular weight or other characterizing features of a protein, **which protein is taught by the prior art**, imparts neither novelty nor unobviousness to the protein. Further, given that the protein(s) was known in the prior art, one of ordinary skill in the art would have been motivated to identify the amino acid sequence, molecular weight and whether or not the protein is glycosylated since proteins are routinely characterized in this manner. Therefore, the proteins of the reference appear to be consistent with those claimed with the various identifying characteristics inherent in them. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and

the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Since the Patent Office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants have asserted that it was unusually difficult to obtain the amino acid sequence. However, such assertions should be made in the form of a declaration with references to support this assertion of unusual difficulty.

8. With regard to the rejections set forth in paragraphs 5-7, they are maintained for the reasons of record as Applicants have not set forth any declarations or arguments found sufficient to overcome these rejections.

9. Claim 20 (canceled) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. Claim 20 is directed to a pharmaceutical composition comprising a protein (SEQ ID NO:1 for example) in combination with a pharmceutically acceptable carrier or extender. The specification has not enabled (how to use) a pharmaceutical composition. Example 1 shows cloning and expression, Example 2 shows cloning and expression of protein LG, and Example 3 shows analysis of binding properties of protein LG. The specification at page 13 describes pharmaceutical additions. It is not known from the specification what disease or infection the pharmaceutical composition is to be used? Will the pharmaceutical composition be used to treat AIDS, cancer, ulcers, Leishmaniasis or some other bacterial, viral, fungal parasitic infection? There are no examples and/or written description of treatment using the pharmaceutical compositions.

For a claim to be enabled the specification must teach how to make and use the claimed pharmaceutical composition without undue experimentation and must teach how to use the pharmaceutical composition for at least one pharmaceutical use without undue experimentation. A pharmaceutical use would be any use of the composition, other than as food, wherein the proteins are used on or in the body to prevent, diagnose, alleviate, treat, or cure a disease in humans or animals. The pharmaceutical use must occur within the human or animal to which the compound is administered for the prevention, diagnosis, alleviation, treatment or cure of a specific disease. The present specification has not set forth such evidence and/or

enablement with regard to the presently claimed invention of a pharmaceutical composition.

10. Applicants should update the references in the specification that refers to "in print"; see for example page 22, line 20. Applicants are encouraged to review the entire application.

11. Claims 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of the various domains and the SEQ ID NO:1 and 3. Applicants should define amino acid sequence position in the SEQ ID NO the set forth the domains (B1, B2, B3, B4 as set forth in claim 14 and the various domains set forth in claim 16).

12. No claims are allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14 Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield
April 23, 2001

NITA MINNIFIELD
PRIMARY EXAMINER